

- 18 -

Claims

1. A method of fabricating a bone substitute material,
the method comprising the steps of:
providing a foam material having an open cell
5 structure,
distorting the shape of the foam material and
holding the material in a distorted shape,
coating the walls of the cells of the foam material
with a ceramic slip,
10 removing the foam material, and
sintering the ceramic slip to form a bone
substitute material that is approximately a positive
image of the distorted foam material.
2. A method according to claim 1, in which the step of
15 distorting the shape of the foam material comprises
stretching the foam material.
3. A method according to claim 2, in which the foam
material is stretched in one direction only.
4. A method according to claim 2 or 3, in which the
20 foam material is permanently deformed.
5. A method according to any preceding claim, in which
the step of removing the foam material comprises heating
the material.
6. A method according to claim 5, in which the method
25 comprises a first heating step in which the foam
material is removed and a second, subsequent, heating
step in which the ceramic slip is heated to a higher
temperature and is sintered.

- 19 -

7. A method according to any preceding claim, in which the step of coating the walls of the cells of the foam material with a ceramic slip includes the steps of immersing the foam material in the ceramic slip and
5 draining some of the ceramic slip from the foam material.
8. A method according to claim 7, in which the immersing and draining steps are repeated.
9. A method according to claim 7 or 8, in which the
10 foam material is mechanically compressed and then allowed to expand while it is immersed in the ceramic slip.
10. A method according to any of claims 7 to 9, in which air is directed onto the coated foam material to
15 inhibit the formation of closed cells.
11. A method according to any preceding claim, in which the foam material is a polymeric foam material.
12. A method according to any preceding claim, in which the ceramic base substitute material has a macroporosity
20 in the range of 40 to 70%.
13. A method according to any preceding claim, in which more than half of the macroporosity of the material is provided by pores having an equivalent diameter in the range of 150 to 450 μm .
- 25 14. A bone substitute material comprising a porous sintered ceramic having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being

- 20 -

hollow, wherein the cellular structure is orientated such that the cells generally have a length in one direction greater than a length in a perpendicular direction.

- 5 15. A bone substitute material according to claim 14, in which the cells are generally of elongate form having a length in one direction greater than their lengths in the two other perpendicular directions.
- 10 16. A bone substitute material according to claim 15, in which the cells have a length in one direction more than 20% greater than their length in the two other perpendicular directions.
- 15 17. A bone substitute material according to any of claims 13 to 16, in which the material has a macroporosity in the range of 40 to 70%.
- 20 18. A bone substitute material according to any of claims 13 to 17, in which more than half of the macroporosity of the material is provided by pores having an equivalent diameter in the range of 150 to 450 μm .
19. A bone substitute material according to any of claims 13 to 18 in which the material has a breaking stress of more than 1 MPa.
- 25 20. A method of fabricating a granular bone substitute material, the method comprising the steps of:
providing a multiplicity of pieces of foam material having an open cell structure, each occupying a space of less than 1000 mm^3 ,
coating the walls of the cells of the pieces of

- 21 -

- foam material with a ceramic slip,
removing the foam material, and
sintering the ceramic slip to form a granular bone
substitute material in which the granules are
5 approximately positive images of the pieces of foam
material.
21. A method according to claim 20, in which the
pieces of foam material have a maximum dimension of less
than 12 mm.
- 10 22. A method according to claim 20 or 21, in which the
pieces of foam material are of irregular shape.
23. A method according to claim 20 or 21, in which the
pieces of foam material are approximately cubes.
24. A method according to claim 23, in which the cubes
15 have sides of length less than 8 mm.
25. A method according to any of claims 20 to 24, in
which the pieces of foam material are all of
substantially the same size.
26. A method according to any of claims 20 to 24, in
20 which the pieces of foam material vary in size and/or
shape.
27. A method according to any of claims 20 to 26,
further comprising the step of treating the granular
sintered material to reduce the size of and/or alter the
25 shapes of the granules.
28. A method according to claim 27, in which the
treating step comprises a milling step.

- 22 -

29. A method according to claim 28, in which the milling step comprises ball milling.

30. A method according to any of claims 20 to 29, in which the step of removing the foam material comprises heating the material.

31. A method according to claim 30, in which the method comprises a first heating step in which the foam material is removed and a second, subsequent, heating step in which the ceramic slip is heated to a higher temperature and is sintered.

32. A method according to any of claims 20 to 31, in which the step of coating the walls of the cells of the pieces of foam material with a ceramic slip includes the steps of immersing the pieces of foam material in the ceramic slip and draining some of the ceramic slip from the pieces of foam material.

33. A method according to claim 32, in which the step of draining some of the ceramic slip from the pieces of foam material comprises the step of supporting the pieces of foam material on a perforated support surface.

34. A method according to claim 32 or 33, in which the immersing and draining steps are repeated.

35. A method according to any of claims 20 to 34, in which the pieces of foam material are mechanically compressed and then allowed to expand while they are immersed in the ceramic slip.

- 23 -

36. A method according to any of claims 20 to 35, in which air is directed onto the coated foam material to inhibit the formation of closed cells.

37. A method according to any of claims 20 to 36, in
5 which the foam material is a polymeric foam material.

38. A method according to any of claims 20 to 37, in which the granular bone substitute material has a macroporosity in the range of 40 to 70%.

39. A method according to any of claims 20 to 38, in
10 which more than half the macroporosity of the material is provided by pores having an equivalent diameter in the range of 150 to 450 μm .

40. A granular bone substitute material comprising a multiplicity of granules of a porous sintered ceramic,
15 each granule having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the granules being hollow and the granule occupying a space of less than 1000 mm^3 .

41. A granular bone substitute material according to
20 claim 40, in which the material has a macroporosity in the range of 40 to 70%.

42. A granular bone substitute material according to claim 40 or 41, in which more than half of the macroporosity of the material is provided by pores
25 having an equivalent diameter in the range of 150 to 450 μm .

43. A granular bone substitute material according to any of claims 40 to 42, in which the material has a

- 24 -

compressive modulus at a load of 500 N of more than 40 MPa.

44. A granular bone substitute material according to any of claims 40 to 43, in which the granules have a
5 maximum dimension of less than 12 mm.

45. A granular bone substitute material according to any of claims 40 to 44, in which the granules are of irregular shape.

46. A granular bone substitute material according to
10 any of claims 40 to 44, in which the granules are approximately cubes. 47. A granular bone substitute material according to claim 46, in which the cubes have sides of length less than 8 mm.

48. A granular bone substitute material according to
15 any of claims 40 to 47, in which the granules have rounded edges.

49. A granular bone substitute material according to any of claims 40 to 48, in which the granules are all of substantially the same size.

20 50. A granular bone substitute material according to any of claims 40 to 48, in which the granules vary in size and/or shape.

51. A bone substitute material of a porous sintered ceramic having approximately the form of a positive
25 image of an open celled foam material, the material having a macroporosity in the range of 40 to 70% and a breaking stress of more than 1 MPa.

- 25 -

52. A method of forming a bone graft comprising the steps of implanting a bone substitute material that is approximately in the form of a positive image of an open celled foam material into or onto a bone.
- 5 53. A method according to claim 52, in which the bone substitute material is granular material.
54. A method according to claim 53, in which the granular bone substitute material is in accordance with any of claims 40 to 50.
- 10 55. A method according to claim 53 or 54, in which the material is implanted into a bone and substantially entirely enclosed therein.
56. A method according to claim 53 or 54, in which the material is implanted into a recess on the surface of
15 the bone.
57. A method according to claim 52, in which the bone substitute material is in the form of a cylindrical block of circular cross-section.
58. A method according to claim 52, in which the
20 material is in the form of a preshaped block and is implanted into a correspondingly shaped space in or on the surface of a bone.
59. A method according to claim 52, in which the material is housed in a cage or other structure which is
25 then implanted.
60. A method according to claim 58 or 59, in which the implant contributes to the structural strength of the bone.

- 26 -

61. A method according to claim 52 or any of claims 57 to 60, in which the bone substitute material is in accordance with any of claims 14 to 19.